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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,760	06/22/2000	Martha K. Newell	10277/7009 HCL	8006

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Boston, MA 02110

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

File

**Office Action Summary**

Application No.

09/599,760

Applicant(s)

Newell, M.

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on Oct 28, 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above, claim(s) 1-59, 65, 73, and 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-64 and 66-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_                      6) ☒ Other: *Notice to Comply*

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### DETAILED ACTION

This Office action is in response to the communications filed October 28, 2002, Paper Nos. 15 and 16.

Claims 1-74 are pending in the instant application.

#### *Request for Continued Examination*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 28, 2002 has been entered.

#### *Sequence Compliance*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequences listed in the specification (e.g. on page 8, lines 15-25) must have appropriate, accompanying SEQ ID NOs. See the accompanying Notice to Comply.**

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***Response to Arguments***

The declaration has been entered and considered but does not overcome the rejection for the reasons set forth in the 35 U.S.C. 112, first paragraph rejection below.

**Maintained Rejections**

Claims 60-64 and 66-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention over the scope claimed, for the reasons set forth in the previous Office action mailed July 12, 2001, Paper No. 11, and reiterated in the Office action mailed April 23, 2002, Paper No. 13.

Applicant's arguments and declaration filed October 28, 2002 have been fully considered but they are not persuasive. Applicant argues that the claimed invention is enabled over the broad scope claimed because UCP2 knockout mice have been generated and lysosomes in such mice have been found to be more acidic and furthermore the knockout mice were found to have increased resistance to infection (e.g. *Toxoplasma gondii*) compared to wild type mice. Contrary to Applicants' assertions, however, the findings observed in UCP2 knockout mice is not enabling for the broad scope claimed. The claims are drawn to methods of regulating lysosomal pH and methods of treating or preventing any infectious disease in any organism, comprising the administration of any lysosomal UCP inhibitor. The ablation or disruption of the UCP2 gene in mice, whereby a decrease in lysosomal pH is obtained, and further whereby resistance to *T. gondii*

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has been obtained, is not representative of the ability to regulate lysosomal pH in any and/or all cells in any and/or all organisms comprising the administration of any lysosomal UCP inhibitor (including a dominant negative construct of lysosomal UCP) by any route of administration, nor are these findings representative of the ability to prevent and/or treat any and/or all infectious diseases in any organism. It would require undue experimentation beyond that which has been provided in the instant disclosure (and including the teachings of Arsenijevic et al) whereby any lysosomal UCP inhibitor (including a dominant negative construct of lysosomal UCP) is administered by any means to any organism, the appropriate cells are targeted, lysosomal pH is regulated and infectious diseases are treated and/or prevented.

*New Rejections*

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-64 and 66-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are drawn to compositions and methods comprising lysosomal UCP inhibitors, including dominant negative forms of lysosomal UCP, lysosomal targeted binding peptides and targeted binding molecules. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising these various lysosomal UCP inhibitors. The scope of the claims includes numerous structural variants, and genus is highly variant because a significant number of structural differences between genus members is permitted. Concise structural features that could distinguish compounds in the genus from others are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific - not general - guidance is what is needed. Since the disclosure fails to describe the characteristics concisely identifying members of the genus, and because the genus is highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to concisely describe the various members of the genus claimed. Thus, Applicant was not in possession of the claimed genus.

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***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
KAREN LACOURCIERE  
PATENT EXAMINER

**JZ**

January 8, 2003